

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

Civil Action No: 1:23-cv-00077

AMY BRYANT, MD,

Plaintiff,

v.

JOSHUA H. STEIN, in his official capacity as Attorney General for the State of North Carolina; JEFF NIEMAN, in his official capacity as District Attorney for North Carolina 18th Prosecutorial District; KODY H. KINSLEY, in his official capacity as the North Carolina Secretary of Health and Human Services; MICHAUX R. KILPATRICK, MD, PhD, in her official capacity as President of the North Carolina Medical Board; and CHRISTINE M. KHANDELWAL, DO; DEVADUTTA G. SANGVAI, MD, MBA; JOHN W. RUSHER, MD, JD; WILLIAM M. BRAWLEY; W. HOWARD HALL, MD; SHARONA Y. JOHNSON, PhD, FNP-BC; JOSHUA D. MALCOLM, JD; MIGUEL A. PINEIRO, PA-C, MHPE; MELINDA H. PRIVETTE, MD, JD; ANURADHA RAO-PATEL, MD; and ROBERT RICH, JR., MD, in their official capacities as Board Members of the North Carolina Medical Board,

Defendants.

**ANSWER
OF**

DEFENDANT JEFF NIEMAN, IN HIS OFFICIAL CAPACITY AS DISTRICT ATTORNEY FOR NORTH CAROLINA 18TH PROSECUTORIAL DISTRICT TO FIRST AMENDED COMPLAINT

NOW COMES Defendant Jeff Nieman, in his official capacity as District Attorney for North Carolina's 18th Prosecutorial District, by and through his undersigned counsel, and hereby answers Plaintiff's First Amended Complaint [DE 82] as follows:

FIRST DEFENSE

ANSWER to COMPLAINT

RESPONSE TO “INTRODUCTION”

1. The allegations in Paragraph 1 are legal conclusions and/or constitute Plaintiff's interpretation of provisions of the Federal Food, Drug, and Cosmetic Act (“FDCA”), to which no response is required. To the extent a response is required, the allegations are denied.

2. The allegations in Paragraph 2 are legal conclusions and/or constitute Plaintiff's interpretations of provisions of the FDCA, to which no response is required. To the extent a response is required, the allegations are denied.

3. The allegations in Paragraph 3 constitute legal conclusions and/or are Plaintiff's interpretation of regulatory actions that the Food and Drug Administration (“FDA”) took regarding mifepristone, to which no response is required. To the extent a response is required, the allegations are denied.

4. Defendant is without sufficient knowledge or information to admit or deny the last allegation in Paragraph 4, and therefore, that allegation is denied. The remaining allegations in Paragraph 4 are Plaintiff's interpretation of a publication which speaks for itself, serves as the best evidence of its own content, and requires no response from Defendant. To the extent a response is required, the allegations are denied.

5. Some of the allegations in Paragraph 5 are Plaintiff's characterizations of regulatory actions that the FDA took regarding the Risk Evaluation and Mitigation

Strategies (“REMS”) for mifepristone and in requiring a Certified Provider Agreement, which speak for themselves, are the best evidence of their own content, and require no response from Defendant. The remaining allegations of Paragraph 5 are legal conclusions, to which no response is required. To the extent that a response is required, the allegations are denied.

6. The allegations of Paragraph 6 are Plaintiff’s characterizations of state statutes and provisions of the administrative code, which speak for themselves, serve as the best evidence of their own content, and require no response from Defendant. The remaining allegations in Paragraph 6 are legal conclusions, to which no response is required. To the extent a response is required, the allegations are denied.

7. Defendant is without sufficient knowledge or information to admit or deny the allegations in Paragraph 7, and therefore, the allegations are denied.

8. Upon information and belief, Defendant admits that medical providers who practice within the State must comply with state laws and regulations. The remaining allegations in Paragraph 8 are legal conclusions and/or constitute Plaintiff’s interpretation of state laws, to which no response is required. To the extent that a response is required, the allegations are denied.

9. The allegations in Paragraph 9 are legal conclusions and/or constitute Plaintiff’s interpretation of a legal opinion and position statement, which speak for themselves, serve as the best evidence of their own content, and require no response from Defendant. Defendant is without sufficient knowledge or information to admit or deny the allegation in Paragraph 9 regarding the burden on Plaintiff and her patients, and therefore,

that allegation is denied. To the extent that a response is required, the allegations are denied.

10. Defendant is without sufficient knowledge or information to admit or deny the allegations in Paragraph 10, and therefore, the allegations are denied.

11. Defendant is without sufficient knowledge or information to admit or deny the allegations in Paragraph 11, and therefore, the allegations are denied.

12. The allegations in Paragraph 12 are legal conclusions, to which no response is required. To the extent that a response is required, the allegations are denied.

13. The allegations in Paragraph 13 relate to the nature of the declaratory and injunctive relief Plaintiff seeks in this action, to which no response is required.

RESPONSE TO “PARTIES”

14. Defendant is without sufficient knowledge or information to admit or deny the allegations in Paragraph 14, and therefore, the allegations are denied.

15. Upon information and belief, the allegation in Paragraph 15 is admitted.

16. It is admitted that Jeff Nieman is the District Attorney for North Carolina's 18th Prosecutorial District, which encompasses Chatham and Orange Counties. It is admitted that he is sued in his official capacity only in this lawsuit. It is admitted that as the District Attorney, Defendant is responsible for the prosecution on behalf of the State of all criminal actions and infractions which, in the exercise of his prosecutorial discretion, he determines require prosecution in the superior and district courts of his prosecutorial district. *See* N.C. Const. art. IV, § 18(1); N.C.G.S. §§ 7A-60, -61 (2023). Except as herein specifically admitted, the allegations in Paragraph 16 are denied.

17. Upon information and belief, the allegation in Paragraph 17 is admitted.
18. Upon information and belief, the allegation in Paragraph 18 is admitted.
19. Upon information and belief, the allegation in Paragraph 19 is admitted.
20. Upon information and belief, the allegation in Paragraph 20 is admitted.
21. Upon information and belief, the allegation in Paragraph 21 is admitted.
22. Upon information and belief, the allegation in Paragraph 22 is admitted.
23. Upon information and belief, the allegation in Paragraph 23 is admitted.
24. Upon information and belief, the allegation in Paragraph 24 is admitted.
25. Upon information and belief, the allegation in Paragraph 25 is admitted.
26. Upon information and belief, the allegation in Paragraph 26 is admitted.
27. Upon information and belief, the allegation in Paragraph 27 is admitted.
28. Upon information and belief, the allegation in Paragraph 28 is admitted.
29. Upon information and belief, the allegation in Paragraph 29 is admitted.

RESPONSE TO “JURISDICTION AND VENUE”

30. The allegation in Paragraph 30 is a legal conclusion, to which no response is required. To the extent that a response is required, the allegation is denied.
31. The allegations in Paragraph 31 are legal conclusions, to which no response is required. Defendant admits that he is the District Attorney for North Carolina’s 18th Prosecutorial District, which encompasses Chatham and Orange Counties. Except as specifically admitted herein, the allegations in Paragraph 31 are denied.
32. The allegation in Paragraph 32 regarding venue is a legal conclusion, to which no response is required. Defendant is without sufficient knowledge or information

to admit or deny the allegation in Paragraph 32 regarding where Plaintiff is located and practices medicine, and therefore, that allegation is denied.

33. The allegations in Paragraph 33 are legal conclusions, to which no response is required. To the extent that a response is required, the allegations are denied.

34. The allegations in Paragraph 34 are legal conclusions and/or constitute Plaintiff's interpretation of a legal opinion and position statement, which speak for themselves, serve as the best evidence of their own content, and require no response from Defendant. Defendant is without sufficient knowledge or information to admit or deny the allegations in Paragraph 34 regarding the impact of the challenged laws on Plaintiff, her patients, her practice, and her ability to practice medicine, and therefore, those allegations are denied. To the extent that a response is required, the allegations are denied.

35. The allegations in Paragraph 35 regarding the ripeness of Plaintiff's claim is a legal conclusion, to which no response is required. Defendant is without sufficient knowledge or information to admit or deny the remaining allegations in Paragraph 35 regarding the impact of the challenged laws on Plaintiff's practice of medicine.

RESPONSE TO "FACTUAL ALLEGATIONS"

A. Statutory and Regulatory Background

36. The allegation in Paragraph 36 is a legal conclusion and/or constitute Plaintiff's interpretation of federal laws, which speaks for themselves, serve as the best evidence of its own content, and require no response from Defendant.

37. The allegations in Paragraph 37 are legal conclusions and/or constitute Plaintiff's interpretation of a federal law, which speaks for itself, serves as the best evidence of its own content, and requires no response from Defendant. To the extent that a response is required, the allegations are denied.

38. The allegations in Paragraph 38 are legal conclusions and/or constitute Plaintiff's interpretation of federal laws, which speaks for themselves, serve as the best evidence of their own content, and require no response from Defendant. To the extent that a response is required, the allegations are denied.

39. The allegations in Paragraph 39 are legal conclusions and/or constitute Plaintiff's interpretation of a cited legal opinion, to which no response is required. To the extent that a response is required, the allegations are denied.

40. The allegations in Paragraph 40 are legal conclusions and/or constitute Plaintiff's interpretation of federal laws, which speak for themselves, serve as the best evidence of their own content, and require no response from Defendant. To the extent that a response is required, the allegations are denied.

41. The allegations in Paragraph 41 are legal conclusions and/or constitute Plaintiff's interpretation of federal laws, which speak for themselves, serve as the best evidence of their own content, and require no response from Defendant. To the extent that a response is required, the allegations are denied.

42. The allegations in Paragraph 42 are legal conclusions and/or constitute Plaintiff's interpretation of federal laws, which speak for themselves, serve as the best

evidence of their own content, and require no response from Defendant. To the extent that a response is required, the allegations are denied.

43. The allegations in Paragraph 43 are legal conclusions and/or constitute Plaintiff's interpretation of federal laws, which speak for themselves, serve as the best evidence of their own content, and require no response from Defendant. To the extent that a response is required, the allegations are denied.

44. The allegations in Paragraph 44 are legal conclusions and/or constitute Plaintiff's interpretation of federal laws, which speak for themselves, serve as the best evidence of their own content, and require no response from Defendant. To the extent that a response is required, the allegations are denied.

45. The allegation in Paragraph 45 are legal conclusions and/or constitute Plaintiff's interpretation of a federal law, which speaks for itself, serves as the best evidence of its own content, and requires no response from Defendant. To the extent that a response is required, the allegation is denied.

46. The allegations in Paragraph 46 are legal conclusions and/or constitute Plaintiff's interpretation of federal laws, which speak for themselves, serve as the best evidence of their own content, and require no response from Defendant. To the extent that a response is required, the allegations are denied.

47. The allegation in Paragraph 47 are legal conclusions and/or constitute Plaintiff's interpretation of a REMS Assessment Draft Guidance, which speaks for itself, serves as the best evidence of its own content, and requires no response from Defendant. To the extent that a response is required, the allegations are denied.

48. Defendant is without sufficient knowledge or information to admit or deny the allegations in Paragraph 48 regarding the number of approved drugs that have REMS with ETASU and the number of drugs that the FDA has approved, and therefore, those allegations are denied. The website cited by Plaintiff speaks for itself, serves as the best evidence of its own content, and requires no response from Defendant. To the extent that a response is required, the allegations are denied.

B. FDA's Approval of Mifepristone and the Mifepristone REMS

49. Defendant is without sufficient knowledge or information to admit or deny the allegations in the first two sentences of Paragraph 49 regarding medication abortion, and therefore, those allegations are denied. The medical journal cited by Plaintiff in the remaining allegations in Paragraph 49 speaks for itself, serves as the best evidence of its own content, and requires no response from Defendant. To the extent that a response is required, the allegations are denied.

50. Defendant is without sufficient knowledge or information to admit or deny the allegations in the first two sentences of Paragraph 50 regarding mifepristone, and therefore, those allegations are denied. The prescribing information document cited by Plaintiff in the remaining allegation in Paragraph 50 speaks for itself, serves as the best evidence of its own content, and requires no response from Defendant. To the extent that a response is required, the allegation is denied.

51. Defendant is without sufficient knowledge or information to admit or deny the first allegation in Paragraph 51 regarding regulatory action by the FDA of mifepristone, and therefore, the allegation is denied. The remaining allegation in Paragraph 51 is a legal

conclusion and/or constitute Plaintiff's interpretation of regulatory actions taken by the FDA in modifying the REMS for mifepristone, which speaks for itself, serves as the best evidence of its own content, and requires no response from Defendant. To the extent that a response is required, the allegation is denied.

52. The allegation in Paragraph 52 is a legal conclusion, to which no response is required. To the extent that a response is required, the allegation is denied.

1. FDA's Initial Approval of Mifepristone in 2000

53. The allegations in Paragraph 53 constitute legal conclusions, are Plaintiff's interpretation of federal law and regulatory actions taken by the FDA, and/or cite to documents attached as exhibits to the Complaint, which speak for themselves, serve as the best evidence of their own content, and require no response from Defendant. To the extent that a response is required, the allegations are denied.

54. Defendant is without sufficient knowledge or information to admit or deny the first allegation in Paragraph 54 regarding the FDA's determinations regarding Mifeprex. The remaining allegation in Paragraph 54 constitutes a legal conclusion and/or is Plaintiff's interpretation federal law and regulatory action taken by the FDA regarding Mifeprex cited therein, which speaks for itself, serves as the best evidence of its own content, and requires no response from Defendant. To the extent that a response is required, the allegation is denied.

55. The allegations in Paragraph 55 are legal conclusions and/or constitute Plaintiff's interpretation of regulatory actions taken by the FDA regarding Mifeprex and the 2000 Prescriber Agreement Form for the same cited therein, which speak for

themselves, serve as the best evidence of their own content, and require no response from Defendant. To the extent that a response is required, the allegations are denied.

56. The allegation in Paragraph 56 cites to a document, the 2000 Prescriber Agreement Form, which speaks for itself, serves as the best evidence of its own content, and requires no response from Defendant. To the extent that a response is required, the allegation is denied.

57. The allegations in Paragraph 57 cite to multiple documents that are attached as exhibits to the Complaint, which speak for themselves, serve as the best evidence of their own content, and require no response from Defendant. To the extent that a response is required, the allegations are denied.

58. The allegations in Paragraph 58 cite to multiple documents that are attached as exhibits to the Complaint, which speak for themselves, serve as the best evidence of their own content, and require no response from Defendant. To the extent that a response is required, the allegations are denied.

2. FDA's Approval of Mifepristone REMS in 2011

59. The allegation in Paragraph 59 cites to federal laws, which speak for themselves, serve as the best evidence of their own content, and require no response from Defendant. To the extent that a response is required, the allegation is denied.

60. Defendant is without sufficient knowledge or information to admit or deny the first allegation in Paragraph 60 regarding FDA approval of REMS for mifepristone, and therefore, the allegation is denied. The remaining allegations in Paragraph 60 cite to federal law and multiple documents that are attached as exhibits to the Complaint, which

speak for themselves, serve as the best evidence of their own content, and require no response from Defendant. To the extent that a response is required, the allegations are denied.

3. FDA's Modification of the Mifepristone REMS in 2016

61. The allegations in Paragraph 61 are legal conclusions and/or constitute Plaintiff's interpretation of regulatory actions taken by the FDA regarding Mifeprex and multiple documents that are attached as exhibits to the Complaint, which speak for themselves, serve as the best evidence of their own content, and require no response from Defendant. To the extent that a response is required, the allegations are denied.

62. Defendant is without sufficient knowledge or information to admit or deny the first allegation in Paragraph 62 regarding the FDA approving changes to the REMS for mifepristone, and therefore, the allegation is denied. The remaining allegations in Paragraph 62 are legal conclusions and/or constitute Plaintiff's interpretation of regulatory actions taken by the FDA regarding the REMS for mifepristone and multiple documents that are attached as exhibits to the Complaint, which speak for themselves, serve as the best evidence of their own content, and require no response from Defendant. To the extent that a response is required, the allegations are denied.

63. The allegations in Paragraph 63 are legal conclusions and/or constitute Plaintiff's interpretation of regulatory actions taken by the FDA regarding the REMS for mifepristone and multiple documents that are attached as exhibits to the Complaint, which speak for themselves, serve as the best evidence of their own content, and require no

response from Defendant. To the extent that a response is required, the allegations are denied.

64. The allegations in Paragraph 64 are legal conclusions and/or constitute Plaintiff's interpretation of regulatory actions taken by the FDA regarding the REMS for mifepristone and a document attached as an exhibit to the Complaint, which speak for themselves, serve as the best evidence of their own content, and require no response from Defendant. To the extent that a response is required, the allegations are denied.

4. FDA's Further Modification of the Mifepristone REMS in 2023

65. The allegation in Paragraph 65 constitutes Plaintiff's interpretation of a court filing and a document attached as an exhibit to the Complaint, which speak for themselves, serve as the best evidence of their own content, and require no response from Defendant. To the extent that a response is required, the allegations are denied.

66. Defendant is without sufficient knowledge or information to admit or deny the allegation in Paragraph 66 regarding materials the FDA reviewed as part of its 2021 review of the REMS for mifepristone, and therefore, the allegation is denied. The remaining allegations in Paragraph 66 constitute Plaintiff's interpretation of a court filing and documents attached as exhibits to the Complaint, which speak for themselves, serve as the best evidence of their own content, and require no response from Defendant. To the extent that a response is required, the allegations are denied.

67. The allegations in Paragraph 67 constitute Plaintiff's interpretation of regulatory actions taken by the FDA regarding the REMS for mifepristone, federal law, and a document attached as an exhibit to the Complaint, which speak for themselves, serve

as the best evidence of their own content, and require no response from Defendant. To the extent that a response is required, the allegations are denied.

68. The allegations in Paragraph 68 constitute Plaintiff's interpretation of regulatory actions taken by the FDA regarding the REMS for mifepristone, federal law, and documents attached as exhibits to the Complaint, which speak for themselves, serve as the best evidence of their own content, and require no response from Defendant. To the extent that a response is required, the allegations are denied.

69. The allegations in Paragraph 69 constitute legal conclusions and/or Plaintiff's interpretation of regulatory actions taken by the FDA regarding the REMS for mifepristone, federal law, and documents attached as exhibits to the Complaint, which speak for themselves, serve as the best evidence of their own content, and require no response from Defendant. To the extent that a response is required, the allegations are denied.

70. The allegations in Paragraph 70 constitute legal conclusions and/or Plaintiff's interpretation of regulatory actions taken by the FDA regarding the REMS for mifepristone, federal law, and documents attached as exhibits to the Complaint, which speak for themselves, serve as the best evidence of their own content, and require no response from Defendant. To the extent that a response is required, the allegations are denied.

71. The allegations in Paragraph 71 constitute legal conclusions and/or Plaintiff's interpretation of regulatory actions taken by the FDA regarding the REMS for mifepristone, federal law, and documents attached as exhibits to the Complaint, which

speak for themselves, serve as the best evidence of their own content, and require no response from Defendant. To the extent that a response is required, the allegations are denied.

72. The allegation in Paragraph 72 constitutes Plaintiff's interpretation of documents attached as exhibits to the Complaint, which speak for themselves, serve as the best evidence of their own content, and require no response from Defendant. To the extent that a response is required, the allegations are denied.

73. The allegations in Paragraph 73 constitute legal conclusions and/or Plaintiff's interpretation of federal law, which speaks for itself, serves as the best evidence of its own content, and requires no response from Defendant. To the extent that a response is required, the allegations are denied.

74. The allegations in Paragraph 74 constitute legal conclusions and/or Plaintiff's interpretation of federal law, which speaks for itself, serves as the best evidence of its own content, and requires no response from Defendant. To the extent that a response is required, the allegations are denied.

75. The allegations in Paragraph 75 relate to a document that speaks for itself, serves as the best evidence of its own content, and requires no response from Defendant. To the extent that a response is required, the allegations are denied.

C. North Carolina Law Imposes Unnecessary and Burdensome Requirements on Plaintiff's Prescribing of Mifepristone that Conflict with the FDA-Approved Regulatory Scheme

76. The allegation in Paragraph 76 is a legal conclusion, to which no response is required. To the extent that a response is required, the allegation is denied.

77. The first allegation in paragraph 77 is a legal conclusion, to which no response is required. To the extent that a response is required, the first sentence in Paragraph 77 is denied. It is admitted that on May 16, 2023, the North Carolina legislature overrode the Governor's veto and passed Senate Bill 20. The remaining allegations in Paragraph 77 constitute legal conclusions and/or are Plaintiff's interpretation of state statutes that speak for themselves, serve as the best evidence of their own content, and require no response from Defendant. To the extent that a response is required, the allegations are denied.

78. The allegations in Paragraph 78 constitute legal conclusions and/or are Plaintiff's interpretation of state statutes and administrative code provisions that speak for themselves, serve as the best evidence of their own content, and require no response from Defendant. To the extent that a response is required, the allegations are denied.

79. The allegations in Paragraph 79 constitute legal conclusions and/or are Plaintiff's interpretation of state statutes and administrative code provisions that speak for themselves, serve as the best evidence of their own content, and require no response from Defendant. To the extent that a response is required, the allegations are denied.

80. The allegations in Paragraph 80 constitute legal conclusions and/or are Plaintiff's interpretation of state statutes that speak for themselves, serve as the best evidence of their own content, and require no response from Defendant. To the extent that a response is required, the allegations are denied.

81. The allegations in Paragraph 81 constitute legal conclusions and/or are Plaintiff's interpretation of state statutes and administrative code provisions that speak for

themselves, serve as the best evidence of their own content, and require no response from Defendant. To the extent that a response is required, the allegations are denied.

82. The allegations in Paragraph 82 constitute legal conclusions and/or Plaintiff's interpretation of regulatory actions taken by the FDA regarding the REMS for mifepristone and federal law, which speak for themselves, serve as the best evidence of their own content, and require no response from Defendant. To the extent that a response is required, the allegations are denied.

RESPONSE TO "CAUSE OF ACTION"

83. Defendant incorporates by reference and specifically reasserts his responses to Plaintiff's allegations as set forth above.

84. The allegations in Paragraph 84 constitute legal conclusions, to which no response is required. To the extent that a response is required, the allegations are denied.

85. The allegations in Paragraph 85 constitute legal conclusions, to which no response is required. To the extent that a response is required, the allegations are denied.

86. The allegations in Paragraph 86 constitute legal conclusions, to which no response is required. To the extent that a response is required, the allegations are denied.

87. The allegations in Paragraph 87 constitute legal conclusions, to which no response is required. To the extent that a response is required, the allegations are denied.

88. The allegations in Paragraph 88 constitute legal conclusions, to which no response is required. To the extent that a response is required, the allegations are denied.

RESPONSE TO "PRAYER FOR RELIEF"

Paragraphs one through four in the Prayer for Relief constitute Plaintiff's requests for relief, to which no response is required. To the extent that a response is required, the allegations in these paragraphs are denied.

SECOND DEFENSE

AFFIRMATIVE DEFENSE – PROSECUTORIAL IMMUNITY

Defendant Nieman asserts absolute prosecutorial immunity as an affirmative defense to the causes of action against him in his official capacity. Plaintiff failed to assert sufficient plausible facts to breach the absolute immunity afforded to prosecutors in connection with prosecutorial decisions and Defendant Nieman pleads that immunity as a bar herein.

THIRD DEFENSE

Defendant Nieman pleads and reserves the right to assert any further defenses against Plaintiff that may become apparent during litigation and discovery.

Submitted, this the 21st day of August, 2023.

JOSHUA H. STEIN
Attorney General

/s/ Elizabeth Curran O'Brien
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CERTIFICATE OF SERVICE

I hereby certify that the foregoing was electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record for the parties in this matter.

Respectfully submitted this the 21st day of August, 2023.

/s/ Elizabeth Curran O'Brien
Elizabeth Curran O'Brien
Special Deputy Attorney General
N.C. Department of Justice